K130391

510(k) Summary
per 21 CFR §807.92

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Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-255-0303 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com		
Date Prepared	February 12, 2013		
Proprietary Name(s)	Emerge™ Monorail PTCA Dilatation Catheter Emerge™ Push Monorail PTCA Dilatation Catheter Emerge™ Over-The-Wire PTCA Dilatation Catheter Emerge™ Push Over-The-Wire PTCA Dilatation Catheter		
Common Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter		
Product Code	LOX		
Classification	Class II, 21 CFR Part 870.5100		
Predicate Devices	Emerge™ PTCA Dilatation Catheter (2.00 – 4.00 mm diameter balloon models)	K113220	March 22, 2012
	Emerge™ PTCA Dilatation Catheter (1.50 mm diameter balloon models)	K121196	August 31, 2012
Device Description	The Boston Scientific Emerge™ PTCA Dilatation Catheter (1.20 mm) is a sterile, single-use, intravascular medical device. The catheter consists of a shaft with a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The Emerge™ PTCA Dilatation Catheter is offered in both Monorail (MR) and Over-The-Wire (OTW) platforms. There is a single radiopaque marker band located under the balloon to aid in positioning the system during the procedure. Coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance. The Emerge™ PTCA Dilatation Catheter (1.20 mm diameter) will be available in balloon lengths from 8 mm to 20 mm.		
Intended Use of Device	The Emerge™ PTCA Dilatation Catheter (1.20 mm diameter) is intended for dilatation of stenosis in coronary arteries or bypass grafts.		

Indications for Use	The Emerge™ Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).
Comparison of Technological Characteristics	The Emerge™ PTCA Dilatation Catheter (1.20 mm diameter) incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate devices, Emerge™ PTCA Dilatation Catheter K113220 (cleared March 22, 2012) and Emerge™ PTCA Dilatation Catheter K121196 (cleared August 31, 2012).
Performance Data	The Emerge™ PTCA Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices. The following biocompatibility and chemical characterization tests were completed on the Emerge™ PTCA Dilatation Catheter: Cytotoxicity — Hemolysis (Direct Contact) Sensitization — Hemolysis (Extract Method) Intracutaneous Reactivity — Complement Activation Acute Systemic Toxicity — Coagulation Materials Mediated Pyrogenicity — In Vitro Hemocompatibility USP Physicochemical — FTIR Analysis (Additional Characterization Tests – residual NPGDA analysis) The following in-vitro performance tests were completed on the Emerge™ PTCA Dilatation Catheter: Effective Length — Balloon Inflation/Deflation Time Shaft Inner and Outer Diameter — Catheter Bond Strength Tensile Balloon Crossing Profile — Tip Pull Test Balloon Preparation, Deployment, and Retraction — Flexibility and Kink Withdrawal into a Guide Catheter — Torque Strength Balloon Rated Burst Pressure — Radiopacity Balloon Fatigue (Repeat Inflations) — Coating Integrity Balloon Compliance — Particulate Evaluation
Performance Data – Clinical	A clinical investigation was conducted for the Emerge PTCA Dilatation Catheter (1.20 mm diameter), called *"EMERGE: **E**valuation of Coronary **Lu**minal Diameter **Enlarge**ment with **E**merge™ 1.20 mm PTCA Dilatation Catheter."*

Clinical Study Purpose	The objective of the EMERGE study was to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter when used to initially treat the stenotic portion of coronary arteries or bypass grafts.
Clinical Study Design	The EMERGE study was a prospective, open label, multi-center, single arm, observational study designed to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter in subjects with stenotic coronary arteries or bypass grafts during percutaneous coronary intervention (PCI). Sixty (60) subjects were treated at 3 US sites with the Emerge 1.20 mm PTCA Dilatation Catheter to pre-dilate coronary arteries or bypass grafts during their index procedure. All subjects were to be screened according to the protocol inclusion and exclusion criteria and were followed through hospital discharge. The primary endpoint was device procedural success consisting of successful delivery, inflation, deflation and withdrawal of the study balloon; no evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline related to the study balloon; final TIMI flow grade of 3 at the conclusion of the PCI procedure. The secondary clinical endpoints measured through hospital discharge included in-hospital MACE (cardiac and non-cardiac death, MI and TVR); in-hospital stent thrombosis within the target vessel; clinically significant arrhythmias requiring intervention. Subjects were followed through hospital discharge.
Demographics and Baseline Lesion Characteristics	**Demographics**: A total of 60 subjects with 67 target lesions were enrolled in the study at 3 US sites. The subject population was predominantly male (71.7%) and Caucasian (95.0%) with an average age of 61 years. Most subjects had a history of medically treated hyperlipidemia (85.0%) and hypertension (93.3%) with a history of PCI (61.7%), myocardial infarction (23.3%), and coronary bypass surgery (18.3%). Medically-treated diabetic subjects accounted for 35% of the subject population, of which 16.7% were insulin-requiring. **Baseline Lesion Characteristics**: The average reference vessel diameter was 2.6 ± 0.5 mm, average minimum lumen diameter was 0.7 ± 0.4 mm, average diameter stenosis was 73.0% ± 12.6%, and average lesion length was 15.5 ± 14.7 mm. Total occlusion was observed in 10.4% (7/67) of target lesions.
Clinical Study Results	**Primary Endpoint (Device Procedural Success)**: As illustrated in **Table 1**, 98.3% (59/60) of subjects and 98.5% (66/67) of lesions achieved device procedural success, including successful delivery, inflation, deflation, and withdrawal of the Emerge 1.20 mm PTCA Dilatation Catheter. Device procedural failure was observed in 1.7% (1/60) of subjects and 1.5% (1/67) of lesions and was related to unsuccessful delivery (i.e., failure to cross a lesion) of the study device. No procedural complications were observed in the intent-to-treat subject population. This included no vessel perforation, no flow-limiting dissection, and no reduction in TIMI flow from baseline. Furthermore, 100% (60/60) of subjects and 100% (67/67) of lesions had a final TIMI flow grade of 3 at the conclusion of the PCI procedure.

Table 1: Primary Endpoint Outcomes

	EMERGE Subjects (N=60)	EMERGE Lesions (N=67)
Device Procedural Success	98.3% (59/60)	98.5% (66/67)
Device Procedural Failure	1.7% (1/60)	1.5% (1/67)
Failure of delivery, inflation/deflation and withdrawal	1.7% (1/60)	1.5% (1/67)
Vessel perforation, flow limiting disection or reduction in TIMI flow	0.0% (0/60)	0.0% (0/67)
Failure of final TIMI flow	0.0% (0/60)	0.0% (0/67)

Numbers are % (Count/Sample Size), and based on number of subjects and lesions with site reported data.

Secondary Clinical Endpoint (Safety Events): As illustrated in **Table 2**, the in-hospital major adverse cardiac events were observed in 5.0% (3/60) of the subjects. The non-Q-wave MI rate was 5.0% (3/60), characterized by elevation of post-procedure creatine kinase-myoglobin band (CK-MB) levels to > 3.0 times upper limit of normal (ULN). The Q-wave MI rate was 0% (0/60). The all-cause death and TVR rates were 0% (0/60). The in-hospital stent thrombosis rate, per Academic Research Consortium (ARC), was 0% (0/60). No clinically significant arrhythmias requiring intervention were observed in this study.

Table 2: Secondary Endpoint Outcomes

	EMERGE Subjects (N=60)
In-hospital MACE	5.0% (3/60)
All Death or MI	5.0% (3/60)
All Death	0.0% (0/60)
MI	5.0% (3/60)
Q-Wave MI	0.0% (0/60)
Non-Q-Wave MI	5.0% (3/60)
TVR, Overall	0.0% (0/60)
TVR, PCI	0.0% (0/60)
TVR, CABG	0.0% (0/60)
TLR, Overall	0.0% (0/60)
TLR, PCI	0.0% (0/60)
TLR, CABG	0.0% (0/60)
TVR Remote, Overall	0.0% (0/60)
TVR Remote, PCI	0.0% (0/60)
TVR Remote, CABG	0.0% (0/60)
In-hospital ARC Stent Thrombosis	0.0% (0/60)
In-hospital Clinical Significant Arrhythmias	0.0% (0/60)

Numbers are % (Count/Sample Size), and based on number of subjects with site reported and CEC adjudicated data.

Clinical Study Conclusion

The results of the EMERGE study support the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter and its intended use as a pre-dilatation catheter in the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).

Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Emerge™ PTCA Dilatation Catheter (1.20 mm diameter) has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific predicate devices, Emerge™ PTCA Dilatation Catheters (1.50 mm and 2.00 – 4.00 mm diameter).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 10, 2013

Boston Scientific Corporation
c/o Ms. Vicky Hagens
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K130391
Trade Name: Emerge™ PTCA Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Standard PTCA Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 7, 2013
Received: June 10, 2013

Dear Ms. Hagens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130391

Device Name: Emerge™ Monorail PTCA Dilatation Catheter
Emerge™ Push Monorail PTCA Dilatation Catheter
Emerge™ Over-The-Wire PTCA Dilatation Catheter
Emerge™ Push Over-The-Wire PTCA Dilatation Catheter

Indications for Use:

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)